



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James A. Patterson

Serial No. 09/766,513

Filing Date: January 19, 2001

Inventor: James A. Patterson et al.

Examiner: Frank I. Choi

Group Art Unit: 1616

To: Commissioner of Patents and Trademarks
Washington, D.C. 20231

AFFIDAVIT UNDER RULE 1.132
COMMERCIAL SUCCESS AND LONGFELT NEED

STATE OF FLORIDA
COUNTY OF SARASOTA

I, Douglas Goodman, being duly sworn, depose and say as follows:

1. That I am president of Biolife, L.L.C., (formerly known as Ecosafe, L.L.C.) ("Biolife"), a Florida corporation, which holds all rights to a unique hemostatic agent and method for arresting the flow of blood from an open wound (the "Invention") as described and claimed in the above-referenced pending U.S. patent application;
2. That Biolife was formed in October of 1999 having as one primary purpose being that of distributing products for use by the public, the military, hospitals and organized sports groups embodying the above-referenced Invention as claimed;
3. That the Invention, which is the subject of this application as claimed, includes the unique combination of a hydrophilic oxyacid salt and a hydrophilic proton donor in anhydrous powder or granular form for the painless immediate stoppage of blood flow from an open wound;

4. That, beginning in August of 2001, when Biolife first introduced and began to market the Invention and that, as of the end of November, 2003, a total of 1.5 million individually packaged doses have been sold at a wholesale dollar volume of approximately \$1.5 million, and that to date in 2003 alone, a total of 1.3 million doses of the Invention in individual blister pack form have been sold and distributed;

5. That, to date, Biolife has expended approximately \$120,000 in total advertising and promotion for the Invention in the form of data sheets, catalogs, print ads and other direct marketing expenditures therefor;

6. That the above sales and commercial success of the Invention is in a market which generally enjoys extreme competition in the form of numerous manufacturers of similar products in this industry, including Medtech Products, Inc., Johnson & Johnson, 3-M, Beiersdorf, Inc., Z-Medica, LLC and Medafor, Inc., any and all of which would have been capable of conceiving virtually any obvious blood flow arresting product which would appear to be marketable;

7. That Biolife has received hundreds of unsolicited testimonials for the QR products embodying the Invention from the different user segments as follows:

- Emergency Room Doctors
- Chronic Recurring Wound Doctors
- Podiatrists
- Industrial Occupational Health Workers
- Professional Sports Trainers
- University Sports Trainers
- Consumers

a sampling of which testimonials are included as Exhibit B;

8. That I am aware of, and have carefully considered, the prior art references applied by the Examiner in formulating his rejection of claims 5 to 13 in the above-referenced application in combining the teachings of Olson, Leveen, Burgeni, Eberl, Masci and Micelli and that these references generally reflect the true state of prior art when considered as singular entities and as combined by the examiner; however, this body of prior art teaching fails to disclose, or render as obvious, the Invention which is characterized as including an effective amount of a hydrophilic oxyacid salt combined with an effective amount of a hydrophilic proton donor material in an anhydrous powder or granular form to promote blood clotting at an open wound site;

9. That, as further evidence that the Invention is unobvious and therefore patentable, one only need compare the features and benefits of the Invention, namely rapidly and certainly effecting stoppage of blood flow from a wound and absent any stinging sensation therefrom;

10. That, in my opinion, the above-outlined market acceptance and commercial success of our hemostatic agent and unsolicited testimonials from a very broad range of users of this product which embodies the Invention as claimed providing immediate and painless stoppage of blood flow from a wound and is clear evidence of the unobviousness and therefore patentability of this Invention.

FURTHER, AFFIANT SAYETH NOT.



Douglas Goodman, President of Assignee

SWORN TO AND SUBSCRIBED before me by Douglas Goodman who is personally known, this 8th day of December, 2003.



Melba Adams Mulder
MY COMMISSION # DD035493 EXPIRES
July 9, 2005
BONDED THRU TROY FAIN INSURANCE, INC.



Melba Adams Mulder
Notary Public